

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCTNOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

SONN & PARTNER PATENTANWÄLTE
Riemergasse 14
A-1010 Vienna
AUTRICHEDate of mailing (*day/month/year*)
05 January 2006 (05.01.2006)Applicant's or agent's file reference
R 43208

IMPORTANT NOTICE

International application No.
PCT/EP2004/006460International filing date (*day/month/year*)
16 June 2004 (16.06.2004)Priority date (*day/month/year*)
17 June 2003 (17.06.2003)

Applicant

INTERCELL AG et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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1211 Geneva 20, Switzerland

Authorized officer

Agnes Wittmann-Regis

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference R 43208	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2004/006460	International filing date (<i>day/month/year</i>) 16 June 2004 (16.06.2004)	Priority date (<i>day/month/year</i>) 17 June 2003 (17.06.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant INTERCELL AG		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 19 December 2005 (19.12.2005)
	Authorized officer Agnes Wittmann-Regis Telephone No. +41 22 338 89 70

PATENT COOPERATION TREATY

From, the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 11 MAY 2005

WIPO

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION See paragraph 2 below

International application No.
PCT/EP2004/006460

International filing date (day/month/year)
16.06.2004

Priority date (day/month/year)
17.06.2003

International Patent Classification (IPC) or both national classification and IPC
C07K14/295, A61K39/118

Applicant
INTERCELL AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/006460

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☒ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☒ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/006460

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 3,11,27 and partially 1,2,4-10,12-26, 28-35

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 3,11,27 and partially 1,2,4-10,12-26, 28-35
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/006460

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. partially: 1,2,4-10,12-35

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	8,9,12-26,28-35
	No: Claims	1,2,4-7,10
Inventive step (IS)	Yes: Claims	none
	No: Claims	8,9,12-26,28-35
Industrial applicability (IA)	Yes: Claims	1,2,4-10,12-16,28-35
	No: Claims	none

2. Citations and explanations

see separate sheet

Reference is made to the following document:

- D1: WOLF K-ET AL: "Chlamydia pneumoniae major outer membrane protein is a surface-exposed antigen that elicits antibodies primarily directed against conformation-dependent determinants" INFECTION AND IMMUNITY, AMERICAN SOCIETY FOR MICROBIOLOGY. WASHINGTON, US, vol. 69, no. 5, May 2001 (2001-05), pages 3082-3091
- D2: WO 02/20047 A (SWANBORG ROBERT H ; WHITTUM HUDSON JUDITH A (US); HUDSON ALAN P (US);) 14 March 2002 (2002-03-14)
- D3: DATABASE EMBL "Chlamydia pneumoniae section 49 of 103 of complete genome" retrieved from EBI accession no. AE001633

The present application deals with Chlamydia pneumoniae antigens that can be used for therapy and diagnosis. The potential antigens have been identified by a screening technology that uses serum from Chlamydia infected patients on a C. pneumoniae genomic expression library.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

According to Rule 66.1 (e) claims for which no international search report has been established need not to be subject of international preliminary examination.

1. Claim 27 (antagonist) has not been searched and is therefore not examined.
2. Claim 1c-e and 3c-e have not been examined because they relate to an extremely large number of possible products.

Claim 1c): An isolated nucleic acid comprising a stretch of 15 bases of a nucleic acid molecule which has 70% identity with a specific nucleic acid (Seq ID No:31) might have nothing in common with this specific nucleic acid since the 15 bases can be derived from the 30% that is not identical.

Claims 1d, e): Searching a nucleic acid that hybridizes to such an undefined nucleic acid is impossible.

Claims 3c-e): see 1c-e).

Re Item IV

Lack of unity of invention

As already mentioned in the reasoning for additional search fees the present application does not comply with the requirements of unity of invention. Only claims related to the first group of inventions have been searched, namely those parts of claims 1, 2, 4-10, 12-35 which relate to nucleic acid Seq ID No:31 or to the corresponding amino acid Seq ID No:91. According to Rule 66.1 (e), only these parts are examined.

The first group of inventions comprises individual peptides derived from Seq ID No:91 (see claim 12, page 76, lines 15-17), they are linked by the common concept being derived from a polypeptide (Seq ID No:91) which is new and inventive.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The priority document pertaining to the present application was not available at the time of establishing this first written opinion. Hence, it is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. If it later turns out that this is not correct, the document cited as "P,X" in the International Search Report could become relevant to assess whether the subject-matter of this application satisfies the criteria set forth in article 33(1) PCT.

1. Novelty

- 1.1 Since the complete genome of *C. pneumoniae* has been sequenced and published (D3) an isolated nucleic acid comprising Seq ID No:31 is obviously not new. To the sequence disclosed in D3 Seq ID No:31 aligns to 100% 1-93:7703-7795. Consequently, the subject-matter of claims 1, 2, 4-7 is not new.
- 1.2 Document D2 discloses on page 7-8 an isolated nucleic acid (Seq ID No:1) and its corresponding amino acid (Seq ID No:2) coding for a protein identified as "cpn0483". Seq ID No:1 comprises the nucleic acid Seq ID No:31 of the present application: 1-93:1994-2086 (100% identity) and thereby destroys novelty for subject-matter of claims 1, 2, 4 and 10.

The subject-matter of claims 1, 2, 4-7 and 10 is not new.

2. Inventive step

- 2.1 As mentioned above does document D2 disclose cpn0483 which falls within the scope of claim 1 of the application.

The document further suggests:

- on page 3 line 5 - page 4 line 31 and claim 15 a pharmaceutical composition comprising cpn0483 (claim 15),
- on page 25 line 10-11, page 26 line 20-27, monoclonal, polyclonal, chimeric, humanized and single chain antibodies directed against cpn0483 (claim 18-22),
- on page 25, line 25-28 as well as page 26, line 1-14 method for producing such mAbs and polyclonal Abs (claims 24, 25),
- on page 26 line 15-19 the corresponding hybridoma cell line (claim 23).

Consequently, the subject-matter of claims 15, 18-25 have been suggested in D1 and are not inventive.

- 2.2 Since the product (nucleic acid comprising nucleic acid with Seq ID No:31) is known in the prior art, standard molecular biological methods like expression cloning, search for interaction partners or the production of functional nucleic acids, namely the subject-matter of claims 8, 9, 13, 14, 16, 28-30, 33-35 are if they are new, not inventive.

The subject-matter of claims 8, 9, 13-16, 18-25, 28-30 and 33-35 are not inventive.

- 2.3 However the fragments derived from Seq ID No:91 and listed in claim 12 are new. In order to analyse whether the requirements for inventive step concerning claim 12 are fulfilled the following problem solution approach is performed.

The closest prior art is represented by the teaching of D1 disclosing that human sera from *C. pneumoniae*-positive donors consistently recognize the major outer membrane protein MOMP. However, there is a structural difference between MOMP and the polypeptide encoded by Seq ID No:91.

The technical problem to be solved by the present application therefore lies in the provision of an alternative antigen derived from *C. pneumoniae* suitable for diagnosis, therapy and vaccine development. The problem has been solved by the provision of the nucleic acid Seq ID No:31, the corresponding amino acid Seq ID No:91 and the following fragment thereof: MKAVVSHKSRTS (see Table 2).

Even though the genome of *C. pneumoniae* is known there has been no pointer

towards the immunogenicity of the 93 base long stretch encoded by Seq ID No:31 or the above mentioned fragment MKAVVSHKSRTS. The same applies to the first medical use of such a molecule, the corresponding antibody or the process for in vitro diagnosis

Consequently, those parts of claims 12, 17, 26, 31 and 32 which are related to Seq ID No: 31, 91 or the fragment MKAVVSHKSRTS do fulfil the requirements of inventive step.

The other fragments claimed in claim 12 have either been merely predicted by a known computer program:

KAVVSHK

IHRQYSSYSLFYSIL

IHRQYSSYSLFYS

or are randomly derived from Seq ID No:31:

RVMKAVVSH

VMKAVVSHKSRTSSI

SIHPQYSSY

No function has been shown for them, they are therefore considered as not to solve the problem.

Consequently, the whole scope of claims 12, 17, 26, 31 and 32, including fragments for which no function has been shown, does not fulfil the requirements of inventive step.

Box No. VIII (iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America)
The declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.

**Declaration of inventorship (Rules 4.17(iv) and 51bis.1(a)(iv))
 for the purposes of the designation of the United States of America:**

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This declaration is directed to international application No. PCT/..... (if furnishing declaration pursuant to Rule 26ter).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

Prior Applications:

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.

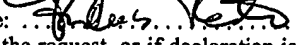
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Citizenship: DE

Inventor's Signature: 
 (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)


Date: 12.02.04
 (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Name: NAGY, Eszter

Residence: Vienna, AT
 (city and either US state, if applicable, or country)

Mailing Address: Taborstrasse 9
 A-1020 Vienna, AT

Citizenship: HU

Inventor's Signature: 
 (if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: 12.02.04
 (of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Continuation of Box No. VIII (i) to (v) DECLARATION

If the space is insufficient in any of Boxes Nos. VIII (i) to (v) to furnish all the information, including in the case where more than two inventors are to be named in Box No. VIII (iv), in such case, write "Continuation of Box No. VIII ..." (indicate the item number of the Box) and furnish the information in the same manner as required for the purposes of the Box in which the space was insufficient. If additional space is needed in respect of two or more declarations, a separate continuation box must be used for each such declaration. If this Box is not used, this sheet should not be included in the request.

Continuation of Box No. VIII(iv):

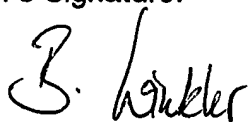
Name: WINKLER, Birgit

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Date:

23.02.04